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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,938	08/21/2001	Pathiraja A. Gunatillake	1207.008US1	7489

7590 06/17/2003
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EXAMINER

SERGEANT, RABON A

ART UNIT PAPER NUMBER

1711

DATE MAILED: 06/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,938

Applicant(s)

GUNATILLAKE ET AL.

Examiner

Rabon Sergeant

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-108,111,112,117-121 and 125-129 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-108,111,112,117-121 and 125-129 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. Claims 81-103 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Adequate support has not been provided for claiming that the molecular weights are number average molecular weights.

The examiner has considered applicants' arguments; however, the arguments are deficient. Firstly, contrary to applicants' response, a copy of the referred to excerpt has not been received. Secondly, the reference to a number average molecular weight in another patent in no way establishes that applicants also used number average molecular weights.

2. Claims 63-103, 117-121, and 125-129 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Despite applicants' response, it remains unclear how the formula (I) soft segment component is to differ structurally from the chain extender of formula (I); in other words, it is not clear that the claim language allows for the respective compounds, based on formula (I), being different. Applicants' response has not clarified this issue.

3. Claims 81-102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Within claim 81, it is improper to define the variable, n, using “about”, because it cannot be determined exactly what compounds are defined or encompassed by the structure, due to the variation or uncertainty that “about” introduces into the structure. For example, it cannot be clearly determined what value is denoted by “about 5”.

4. Claims 63-103, 117-121, and 125-129 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Within line 5 (the formula constituting one line) of claim 63, “a a” is present.

5. Claims 80 and 84-102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The subject matter of claims 80, 84, 85, and 95 fails to further the claims.

6. Claims 104-108 and 112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Markush group of chain extenders for the second chain extender contains compounds that are met by the structure of the first chain extender; therefore, it is unclear how to interpret the requirement that two chain extenders are used.

7. Claims 125-129 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Adequate support has not been provided for the claiming of the recited degradation rankings and the cycle flex fatigue resistance values, because the values were determined using a composition that does not correspond to the composition of claim 63. The data is based on composition 2 of example 3; however, this composition has not been derived from the claimed macrodiamine component. Furthermore, the position is taken that there is inadequate support for claiming the ranges of the degradation values, since the values are not recited as ranges, only data points within Table 5. These points are inadequate to establish that applicants were in possession of the entire range at the time of invention.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 63-108, 111, 112, 117-121, and 125-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szycher et al. ('627) or WO 98/13405 or JP 4-248826, each in view of Li et al. ('724) and Ohtaki et al. ('085).

The primary references disclose the production of polysiloxane-polyurethane (urea) polymers having enhanced biocompatibility wherein active hydrogen group containing polysiloxanes are combined with additional active hydrogen compounds, such as polyethers or polycarbonates, and the resulting mixtures are reacted with polyisocyanates to yield polymers having enhanced characteristics.

10. While Szycher et al. and JP 4-248826 disclose that amine functional polysiloxanes may be used, the references further disclose the use of hydroxyl functional polysiloxanes.

Additionally, none of the primary references disclose the specific use of an amine functional siloxane as a chain extender. However, Li et al. specifically teach the use of amine functional polysiloxane compounds, which overlap applicants' claimed soft segment and hard segment compounds, in the production of biocompatible polyureas and polyurethane ureas having improved physical and mechanical properties. Furthermore, Ohtaki et al. disclose the amino functional tetraorganodisiloxanes as modifying reactants within polyurethanes.

11. Therefore, since applicants' claimed amine functional polysiloxanes were known reaction constituents for polyurethaneurea and since they were known to bestow improved properties,

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including improved biocompatibility, to urethanes, it would have been *prima facie* obvious to utilize them as reactants within the compositions of the primary references, so as to arrive at the instant invention.

12. Applicants' arguments of March 28, 2003 have been considered; however, the position is maintained that the arguments fail to appreciate the significance of the teachings of the secondary references and fail to consider the scope of the instant claims' limitations. The position is taken that applicants' claims do not differentiate the soft segment compound of formula (I) with the hard segment compound of formula (I); therefore, the references need merely teach the desirability of incorporating an amine functional polysiloxane which meets the claimed formula (I) into a polyurethaneurea. The secondary references clearly provide this teaching.

Furthermore, it would have been obvious to utilize the amine functional siloxane within either or both of the reaction components of the instant composition, because one would have reasonably expected the amine functional polysiloxane to convey beneficial properties to the composition, regardless of its means of introduction. Applicants' arguments have not addressed these positions.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (703) 308-2982.

R. Sergent
June 14, 2003


RABON SERGENT
PRIMARY EXAMINER